K081116

X. PREMARKET NOTIFICATION SUMMARY

SEP - 2 2008

Submitted by:

Vitrolife Sweden AB
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SWEDEN

Contact Person:

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Date Prepared:

7 July 2008

Trade Name:

G-IVF™/G-IVF™ PLUS

Common Name:

IVF Media

Classification Name:

Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Device:

G-FERT™ GIII Series (K022245)

Description of the Device:

The IVF Media G-FERT™ in the so called GIII Series has been on the market for a number of years and Vitrolife Sweden AB has now made some product changes in order to further improve the robustness of this media. This improved media is called G-IVF™/G-IVF™ PLUS

G-IVF™/G-IVF™ PLUS is used for preparation and handling of gametes and for in vitro fertilization

Intended Use:

G-IVF™/G-IVF™ PLUS is intended for preparation and handling of gametes and for in vitro fertilization

Technological Characteristics:

G-IVF™/G-IVF™ PLUS is a device used for preparation and handling of gametes and for in vitro fertilization. G-IVF™ PLUS contains HSA which has been added during the manufacturing, while HSA has to be added to G-IVF™ by the clinics before use.

G-IVF™/G-IVF™ PLUS is a modification of the device G-FERT™ (K022245). The technological characteristics of G-IVF™/G-IVF™ PLUS are essentially similar to those of the predicate device. None of the differences between the predicate device and G-IVF™/G-IVF™ PLUS do raise any new questions of safety or effectiveness.

For the new product G-IVF™/G-IVF™ PLUS a name change (from G-FERT™) has been made in order to avoid a mix-up between the two versions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

Mr. Kjell Kjörk
Pharmacist, Regulatory Affairs Manager
Vitrolife Sweden AB
Faktorvägen 13
SE-434 37 Kungsbacka
SWEDEN

Re: K081116
Trade/Devices Name: G-IVF™ PLUS
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: August 12, 2008
Received: August 15, 2008

Dear Mr. Kjörk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081116

Device Name: G-IVF™ PLUS

Indications for Use:

G-IVF™ PLUS is indicated for preparation and handling of gametes and for in vitro fertilization

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use_____
(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081116